510(k) Summary

Date: 01/21/2009

APR 24 2009

Company:

510(k) owner	**Neusoft Positron Medical Systems Co., Ltd.**
Address	No.16 Shiji Road, Hunnan New District, Shenyang, P.R. China
Telephone	86-24-83662197
Fax	86-24-83661796
Contact	Sun Yan, Chief Quality Engineer, Quality Management Department
U.S. Agent	**Delphi Consulting Group**
Contact	J. Harvey Knauss
Telephone	713-723-4080
Fax	713-723-0786
E-Mail	harvey.knauss@gmail.com

Device:

Trade Name	Attrius™, Attrius L™, Truesight
Common Name	Positron Emission Tomography (PET) Scanner
Classification Name	System, tomography, computed, emission
Device Class	21 CFR 892.1200 Class II
Product Code	KPS
Classification panel	Radiology
Predicate Device	K022001, mPower, Model 712, Positron Corp.

Device description summary:

The Positron Emission Tomography (PET) scanners from Neusoft Positron Medical Systems Corporation image the distribution of positron-emitting radionuclides in the human body. These software-controlled medical devices use positron emitting radioactive isotopes to create cross-sectional tomographic images that show function or metabolism, rather than anatomy, as in conventional scanning techniques.

The PET scanner's software generates quantitative images through Attenuation Correction, which corrects for loss of information due to absorption and scatter by overlying soft tissue, and through theoretical, measured, or hybrid (segmented attenuation correction) Image Reconstruction, which generates transaxial images from acquired data using a filtered back projection or iterative reconstruction process.

The PET scanner consists of Detector System, Gantry, Front-end Electronics, Patient Table, Transmission Source, Operator's Control Workstation, Image Processing Workstation and optional Remote Display Workstation.

Intended Use:
The PET scanner is intended to be used for whole body, multi-slice, Positron Emission Tomography diagnostic imaging.

Environment of Use / Patient Population:
The PET scanner is intended to be used for imaging individual patients in a controlled medical facility, such as a hospital, medical clinic, or mobile medical unit environment.

Comparison of Major Technological Characteristics:

The main design differences between the predicate device, the mPower™ PET scanner, and the candidate device, the NPMS PET scanner, are listed below:

1. The system hardware dead time of the candidate device is reduced relative to the predicate device, e.g., the predicate device has a Discriminator dead time period of 520 nanoseconds, whereas the candidate device Discriminator dead time period is 400 nanoseconds; the predicate device has a coincidence dead time period of 160 nanoseconds and encoder dead time period of 42 nanoseconds, whereas the candidate device has a coincidence dead time period of 60 nanoseconds and encoder dead time period of 30 nanoseconds.
2. The predicate device Front End Electronics include 64 Discriminator boards, 8 Encoder boards, 4 LAFD boards, 1 Coincidence board, and 1 Arbitration and Transfer board, whereas the candidate device integrates the same functionality into 8 Bank Encoder Boards (BEB) and 1 Data Assembly Board (DAB) .
3. The predicate device uses 34 fans and blowers to pull cooling air through the Gantry and Front End Electronics enclosures. The candidate device uses 4 fans located in the top cover of the Gantry to pull cooling air through the Gantry.
4. The predicate device rod source loading mechanism requires manual intervention to switch between the high activity transmission rod source and low activity emission calibration rod source whereas the candidate device provides an automated rod source loading mechanism that loads either the high activity transmission rod source or the low activity emission calibration source without manual intervention.

5. The predicate device has a single LED display on the front cover of the Gantry along with two pushbutton control panels. The candidate device has two LCD displays combined with pushbutton control panels on the front cover of the Gantry, along with two pushbutton control panels on the sides of the Gantry (accessible from behind the Gantry), and an LED display on the rear cover of the Gantry.
6. The predicate device provides a stop switch which makes the device slow down and stop gradually, whereas the candidate device provides emergency stop switches which shut off the power of table, septa and wobble, and so the moving components of the device stop quickly.
7. The predicate device patient table weight limit is 159 kg. The candidate device patient table weight limit is 200 kg.
8. The predicate device patient table is a fixed height design. The candidate device patient table can move over a 24cm vertical range from a loading level to a working level.
9. The predicate device utilizes one Ge-68 4mCi transmission rod source. The candidate device utilizes one Ge-68 5mCi transmission source.
10. The candidate device includes an updated control workstation and image processing workstation.
11. The predicate device data acquisition system is a rack mounted VMEbus-based real time computer running the VxWorks real-time operating system on a MC68030-based single board computer. The data acquisition and processing functions are executed on a set of proprietary VME/VSBbus compatible boards. The candidate device provides a Gigabit Ethernet interface on the Data Assembly Board that transfers the event data and system control data to the control workstation where the data are processed by software.
12. The candidate device provides the same 3rd party OSEM image reconstruction software used on the predicate device. In addition, the candidate device uses the following 3rd party software: Linux Operating System, RTAI (Real Time Application Interface). These 3rd party software packages were not used on the predicate device.
13. The performance test data of the candidate device have been obtained using NEMA NU2 phantoms, under the test procedure of NEMA NU2 standards and detailed in section 18 of the submission.

Testing

The following tests can demonstrate the candidate device is as safe, as effective, and performs as well as or better than the predicate device:

- Radiation measurement
- NEMA NU2 Performance test
- IEC 60601-1 Safety tests
- IEC 60601-1-1 Safety tests
- IEC 60601-1-2 Electromagnetic Compatibility test
- Software validation, US FDA Software Used in Medical Devices Guidance

Conclusions:

All the above differences have been verified and determined to not affect safety and effectiveness of the device. We submit that the candidate device and the predicate device are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 4 2009

Mr. Sun Yan
Chief Quality Engineer, Quality Management Department
Neusoft Positron Medical Systems Co., Ltd.
No., 16, Shiji Road, Hunnan New District
Shenyang, Liaoning. 110179
P. R. China

Re: K090178
Trade/Device Name: Attrius™, Attrius L™, Truesight PET scanner
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: January 26, 2009
Received: January 26, 2009

Dear Mr. Yan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

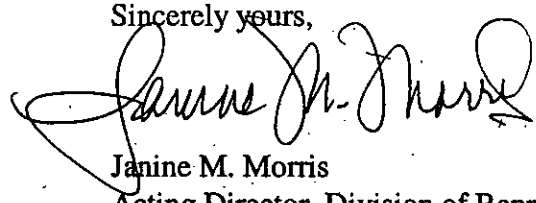
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use statement

510(k) Number: K090178

Device Name: Attrius™, Attrius L™, Truesight PET scanner

Intended Use / Indications for Use:

The PET scanner is intended to be used for whole body, multislice, positron emission tomography diagnostic imaging.

Environment of Use / Patient Population:

The PET scanner is intended to be used to image individual patients in a controlled medical facility, such as a hospital, medical center, or mobile medical unit environment.

Prescription Use YES (Part 21 CFR 801 Subpart D)

Over-The-Counter Use NO (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090178